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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/830,300      | 07/05/2001  | Achim Berthold       | R00282US (#90568)   | 8251             |

28672 7590 12/20/2002  
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EXAMINER

GOLLAMUDI, SHARMILA S

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,300

Applicant(s)

BERTHOLD, ACHIM

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- Th MAILING DATE of this communication app ars on the cov r sh t with th correspond nce address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of Amendment B, Extension of Time, and Information Disclosure received on October 3, 2002 is acknowledged. Claim 15 is included in the prosecution of this application. Claims 8-14 are withdrawn from prosecution. Claims 1-5 and 7 are cancelled.

### ***Election/Restrictions***

Newly submitted claims 8-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claims recited a process for manufacturing a therapeutic system comprising laminating at least two polymer layers with different Tg upon each other and a method of providing therapeutic application by means of applying a therapeutic system containing at least two different polymers with different Tg. New claims submitted recite a distinct invention, i.e. a method of improving cohesion of at least two polymers layers of a transdermal system by reducing cold flow. This invention has a different function and effect; i.e. improving cohesion versus process of making and method of therapeutic application.

In regards to the argument that new method claims incorporate former claim 5, the examiner points out that no where in former claim 5 does the instant claim recite improving cohesion by reducing cold flow. This is a different technical feature, which was not originally presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-14 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**New claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Kydonieus et al (5580573).**

Kydonieus et al teach a temperature controlled polymeric device. The device is used for topical application (col. 3, lines 11-13 and claim 4). The device can be constructed in three types, one being a combined monolithic reservoir (Note Fig. 3). In this system a rate-controlling polymer encapsulates the active-polymer layer (col. 2, lines 56 to col. 3, line 5). The rate-controlling layer has a T<sub>g</sub> in the range of 20 to 50 degrees. The non-rate controlling polymer containing the active agent has a low T<sub>g</sub>. The polymeric components of the device have high molecular weights. (Note col. 3, lines 25-57).

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Kydonieus et al teach a device for controlled release of biologically active substances wherein the release is temperature activated.

The examiner points to figure 3 in which the reference teaches a device containing at least two different polymers, i.e. a rate-controlling polymer and a non-rate controlling polymer. The rate-controlling polymer has a different Tg (PVP, polystyrene) and the non-rate controlling polymer has a different Tg (polyisobutylene and polysiloxanes) (Note col. 3, lines 25-55). Therefore, Kydonieus meets the broad recitation of a transdermal system containing at least two polymer layers of different glass temperatures.

**New claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Chien et al (5023084).**

Chien et al disclose a transdermal system containing a backing layer, a polymer layer, and an adhesive layer (Note example 8). The first layer contains an active agent and polyacrylic adhesive (reservoir layer), the second layer contains polyisobutylene polymer (high molecular weight polymer), and the third layer contains polyacrylic adhesive and an active agent (example 8). Further, the example teaches laminating the polymer layers. The active agent is administered in a controlled manner (col. 10, lines 35-46). Chien et al teach the method of estrogen therapy by placing the system on the skin of a subject (Note claims).

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that although Chien teaches a trilayer transdermal system, the function of the function of the separating layer is to decelerate the rate of transmission of the estrogen in the polymer layer with no regard to different glass transition

temperature. It is argued that the reference discloses that the trilayer system need not contain different polymers.

The examiner points out that example 8 teaches the use of two different polymers, which is enough to anticipate the instant invention since instant claim only recite the use of a transdermal system, which includes applying a system that contains two different polymers of different glass transition states to the skin. Although, the glass temperature of each polymer is not specified, the two polymers are different and inherently have different glass transition temperatures.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

*[Handwritten initials]*

December 16, 2002



MICHAEL G. HARTLEY  
PRIMARY EXAMINER

~~MICHAEL G. HARTLEY~~  
~~PRIMARY EXAMINER~~